DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/02/2009 has been entered.

Applicants' amendment of claim 14 has overcome he rejection of claims 14-19 under 35 U.S.C. 112 second paragraph.

Claims 1-3, 5-10, 12-19 and 21 are being considered on the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-10, 12-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Labeille et al. (US 2002/0037342; hereinafter R1).

3. R1 discloses a multi-enzyme product containing glucoamylase, proteolytic and xylanase activities. The product is prepared through the solid state fermentation of wheat bran using *Aspergillus niger*. The product is useful as animal feed. (Abstract).

4. R1 discloses that wheat bran is used as the starting material which is moistened and heat treated to pasteurize it [0025, 0027].

5. R1 teaches adjusting the pH of the substrate to improve the efficiency of the pasteurization process and the initiation of the desired fermentation [0028].

6. R1 discloses that the fermentor should be aerated in order to supply the oxygen necessary for fermentation and to avoid the excessive accumulation of carbon dioxide produced by fermentation [0035]. Given that the fungus utilizes the carbon source for metabolism, a substantial quantity of dry matter is lost in the form of carbon dioxide. As a result the nitrogen content of the substrate will increase due to the loss of dry matter. The quality and digestibility of the protein source will improve due to the action of the proteolytic enzyme. Therefore, the decrease in dry matter and fat content and the increase in nitrogen content with an improved nutritional quality are all inherent in the fermentation process.

7. R1 discloses that the product of the fermentation process is a solid product [0037]. Given that the substrate and the fungus interact to produce a solid product, the solid state fermentation concept applies.

8. R1 discloses that a possible use of the product is the production of wheat-based feed for monogastric animals such as poultry and pigs. In this application, it is the xylanase activity which constitutes the most important factor. [0038] Given this disclosure by R1, grain by products of the fermentation industry can be converted to highly nutritious materials for feeding animals.

9. R1 teaches of freezing or drying the product for storage [0039]

10. R1 teaches that at the end of the fermentation process, the enzymes produced during the course of fermentation can be solublized in aqueous medium and separated by filtration [0082]. Given that the produced enzymes can be separated from the fermented substrate, it is clear that it can be frozen or dried for future use. It is also clear that the enzyme can be delivered using a feed-grade carrier as presently claimed.

11. R1 discloses that an increase is observed in the soluble nitrogen content of the fermented bran due to the proteolytic activity. [0143] The results indicate that the fermented bran is capable of hydrolyzing wheat flour with the same efficacy as a standard preparation [0144]. Therefore, it is clear that the by-products or residue of the alcoholic fermentation of grains used in the solid state fermentation, as disclosed by R1, will have increased digestibility of proteins in the feed.

12. It is noted that R1 does not expressly or impliedly disclose the percent decrease in dry matter, or fat content of the fermented material; neither does it mention an increase in the protein content of the fermented feed. However, since the solid state fermentation employed by R1 uses *Aspergillus niger* and the substrate as presently claimed for a period of time sufficient to cause the induction of xylanase, glucoamylase and protease, it is clear that the decrease in dry matter and fat and an increase in protein content at levels as presently claimed would be inherent in the fermented product.

13. It is also noted that in a solid state fermentation as disclosed by R1, the aerobic fermentation of cereal grain residue will bring about the activity of carbohydrases such as xylanase. This specific enzyme is a key enzyme in improving the nutritional quality of

by-products of cereal grains due to its action on hemicellulase and xylans abundant in cereal grains. Additionally, the protease as disclosed by R1 will cause the solubilization of proteins contained in grain residues resulting in increased nutritional quality of such products. However, the aerobic solid state fermentation of grain materials, as disclosed by R1, needs energy for the metabolizing fungus. As a result, carbohydrates, fats and proteins will be consumed by the fungus with concomitant production of carbon dioxide and ammonia; which brings about decrease in dry matter, fat content and proteins. However, due to loss of carbohydrates and fats at a higher rate, the protein content of the fermented protein will show an increase due to decrease in carbohydrates and fats.

14. R1 discloses that the incorporation of fermented bran into poultry feed made it possible significantly to reduce the feed conversion ratio [0159]. This means that the animal gains weight while consuming a lower quantity of feed.

15. R1 discloses that the use of the fermented bran nevertheless has the advantage of being less expensive than the use of the commercial enzymatic product [0159].

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that Labeille (R1) focuses exclusively on the enzyme content of its end product, rather the giving any consideration to improving nutritional quality of the fermentation substrate itself as is expressly taught by the present disclosure.

a. R1 clearly discloses that loss of dry matter is linked to the growth of fungus. Please see [0123]. The data presented by R1 for the range of decrease in dry matter clearly overlaps the presently claimed range of 7-12%. (Please see R1 Table 6). The claimed ranges for protein and fat content of the fermented product will be inherent regarding the fermentation duration range of 0-63 hours as disclosed by Labeille. On the other hand, the xylanase enzyme as disclosed by R1 will be a key enzyme in increasing the nutritional quality of the grain based fermentation by-products due to hydrolysis of hemicellulose and xylan. The hydrolysis of lignocellulosic materials and proteins as disclosed by R1 will inherently improve the nutritional quality of animal feed.

b. Labeille discloses a process for solid state fermentation of fibrous materials using filamentous fungi in which multiple enzymes including the presently claimed protease are produced. Enzymes are the focus of certain embodiments of the invention, however, Labeille clearly demonstrates the use of the fermented material as animal feed emphasizing the improved nutritional quality of the product with specific reference to reduction in the feed conversion ratio resulting in the weight gain by the animal. Therefore, Labeille discloses all aspects of the presently claimed invention.

2. Applicants argue that Labeille is silent on any changes in protein or fat content of the by-product or residue according to the ranges set forth in the present claims.

a. Applicants' attention is drawn to the biochemistry of the solid state fermentation involving filamentous fungi. Usually in such fermentations the carbon to nitrogen ratio is greater than 1. The reason is of-course the higher requirement for carbon source. In the aerobic fungal fermentation of cellulosic (fibrous) substrates, plenty of carbon dioxide is

evolved due to the metabolism of carbohydrates. This will cause a pronounced decrease in the dry matter of the materials being fermented. This fact is clearly disclosed by Labeille in paragraph [0123]. Labeille also discloses an increase in soluble nitrogen due to the proteolytic action inherent in the fermentation. [0143]. Lipid materials will also be metabolized and a decrease in lipid materials will also be inherent in the fungal fermentations. The induction of lipases is also inherent in the solid state fermentation using *Aspergillus niger*. The decrease in lipids will, of course, depend on the lipid content of the starting material. However, while nitrogenous materials contained in the substrate being fermented, are metabolized, they are mostly utilized by the fungus for synthesis of new cellular materials, enzymes and compounds requiring nitrogen in their structures. It is clear that decrease in dry matter involving carbon sources (carbohydrates and fats) will inherently increase the protein content based on the dry matter. Therefore, while Labeille is not expressly mentioning protein and fat content, percent by weight, the process as disclosed by Labeille will necessitate the inherent biochemical changes in carbohydrates, fats and proteins as presently claimed.

3. Applicants argue that the enzyme focus of the Labeille disclosure is the enzyme content not the nature of substrate.

a. In a specific embodiment, Labeille discloses the improved nutritional quality of the fermented cellulosic substrate and concludes that the supplemented feed shows a decrease in the feed conversion ratio. In other words, more weight is gained by the animal upon consuming less feed.

On the other hand since the fungal fermentations will cause the fibrous agricultural by-products to increase in protein, it is clear that the improved nutritional quality will be an inherent property of such fermented products. Further, it should be realized that enzymes are not induced unless appropriate substrates are present in the fermentation, therefore, Labeille focus on enzymes will include an inherent disclosure of the nature of substrates.

6. Applicants argue regarding any prospective consideration of obviousness of the independent claims over Labeille.

a. The present ground of rejection is that Labeille anticipates the presently claimed invention. Any argument regarding obviousness is irrelevant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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